IFW

200.1133CON5



UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Benjamin OSHLACK, et al.

Serial No.:

10/700,906

Examiner:

To be Assigned

Art Unit:

1615

Filed:

November 4, 2003

For:

TAMPER-RESISTANT ORAL OPIOID

AGONIST FORMULATIONS

<u>PETITION TO ESTABLISH PRIOR RECEIPT IN THE U.S.P.T.O. OF ITEM(S)</u> <u>CONSIDERED AS OMITTED</u>

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 October 4, 2004

Sir:

Applicant petitions the Commissioner for Patents that the omitted item(s), page 50 of the specification, as noted in the Notice Of Omitted Items, dated September 28, 2004, a copy of which is enclosed, was in fact deposited in the U.S. Patent and Trademark Office with the nonprovisional papers on November 4, 2003. Applicant has enclosed a copy of the submitted item, page 50, which was included in the 86 page specification, claims, and abstract portion of the application, and a copy of the return postcard reflecting the receipt of the 86 pages, as evidence of such deposit.

A check for \$130.00 is enclosed which covers the petition fee in accordance with 37 C.F.R 1.17(h).

10/07/2004 HDEMESS1 00000045 10700906

01 FC:1460

130.00 OP

Applicant respectfully requests that, upon grant of the petition under 37 C.F.R. 1.182, the petition fee be refunded, and the Commissioner is hereby authorized to credit the refund to Deposit Account No. 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

Dobart I. Dorodisc

Reg. No. 41,240

Davidson, Davidson & Kappel, LLC 485 Seventh Avenue, 14th Floor New York, N.Y. 10018 (212) 736-1940

FORM PTO -1083 BOX: Missing Parts

COMMISSIONER FOR PATENTS

Alexandria, VA 22313-1450

Docket No.: 200.1133CON5 Date: October 4, 2004

In re application of:

Benjamin OSHLACK et al.

Serial No.:

10/700,906

Filed:

November 4, 2003

For:

TAMPER-RESISTANT ORAL OPIOID AGONIST FORMULATIONS

Sir:

Transmitted herewith is a Petition to Establish Prior Receipt of Omitted Items in the above-identified application.

[]	Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.
[]	Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.
[X]	No fee for additional claims is required.
ij	A filing fee for additional claims calculated as shown below, is required:

	(Col. 1)	(Col. 2)	_	SMALL	ENTITY		LARGE ENTITY
FOR:	REMAINING	HIGHEST		RATE	FEE	<u>OR</u>	RATE FEE
	AFTER	PREVIOUSLY	PRESENT	_			
	AMENDMENT	PAID FOR	EXTRA				
TOTAL CLAIMS	* Minus** 20=			lx \$ 9	<u> \$ </u>		<u> x \$ 18 \$</u>
INDEP. CLAIMS	* Minus*	** 3 =		x \$	\$		x \$ 84 \$
[] FIRST PRESENTATION OF MULTIPLE DEP. CLAIM + \$ \$ + \$280 \$							
[] FIRST PRESENTATION OF MULTIPLE DEP. CLAIM + \$ \$ + \$280 \$							

TOTAL: TOTAL: \$ OR

- If the entry in Co. 1 is less than the entry in Col. 2, write "0" in Col. 3.
- If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
- If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.
- [X] Also transmitted herewith are:
 - [X] Petition for extension under 37 C.F.R. 1.136 (2 pages)
 - [X] Other: Copy of Notice of Omitted Items (2 pages) Page 50 of the Specification (1 page) Copy of the returned postcard (1 page)
- [X] Check(s) in the amount of \$ 130 .00 is/are attached to cover:

[] Basic filing fee

[X] Petition fee under 37 C.F.R. 1.136

[] Other:

- The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this [X] communication or credit any overpayment to Deposit Account No. 50-0552.
 - Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check [X] submitted herewith.

Any patent application processing fees under 37 C.F.R. 1.1 [X]

Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and [X] it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

Robert J. Paradiso, Red.No.41,240 DAVIDSON, PAVIDSON & KAPPEL, LLC

485 Seventh Avenue, 14th Floor New York, New York 10018

Tel: (212) 736-1940

Fax: (212) 736-2427

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service with sufficient postage as "first class mail" in an envelope addressed to Mail Stop: Missing Parts, Commissioner for Patents, P.O.Box 1450, Alexandria, VA 22313-1450" on October 4, 2004.

beth Pietrowski



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. DOI 1450 Alexandria, Viginia 22313-1450

APPLICATION NUMBER FILING OR 371 (c) DATE FIRST NAMED APPLICANT ATTORNEY DOCKET NUMBER 10/700,906 11/04/2003 Benjamin Oshlack 200.1133CON5

DAVIDSON, DAVIDSON & KAPPEL, LLC 14th Floor 485 Seventh Avenue New York, NY 10018 CONFIRMATION NO. 1129
FORMALITIES LETTER
OC000000013919309

Date Mailed: 09/28/2004

NOTICE OF OMITTED ITEM(S) IN A NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

A filing date has been accorded to the above-identified nonprovisional application papers; however, the following item(s) appear to have been omitted from the application:

- Page(s) 50 of the specification (description and claims).
- I. Should applicant contend that the above-noted omitted item(s) was in fact deposited in the U.S. Patent and Trademark Office (USPTO) with the nonprovisional application papers, a copy of this Notice and a petition (and \$130.00 petition fee (37 CFR 1.17(h))) with evidence of such deposit must be filed within TWO MONTHS of the date of this Notice. The petition fee will be refunded if is determined that the item(s) was received by the USPTO.
- II. Should applicant desire to supply the omitted item(s) and accept the date that such omitted item(s) was filed in the USPTO as the filing date of the above-identified application, a copy of this Notice, the omitted item(s) (with a supplemental oath or declaration in compliance with 37 CFR 1.63 and 1.64 referring to such items), and a petition under 37 CFR 1.182 (with the \$130.00 petition fee (37 CFR 1.17(h)) requesting the later filing date must be filed within TWO MONTHS of the date of this Notice.

Applicant is advised that generally the filing fee required for an application is the filing fee in effect on the filing date accorded the application and that payment of the requisite basic filing fee on a date later than the filing date of the application requires payment of a surcharge (37 CFR 1.16(e)). To avoid processing delays and payment of a surcharge, applicant should submit any balance due for the requisite filing fee based on the later filing date being requested when submitting the omitted items(s) and the petition (and petition fee) requesting the later filing date.

III. The failure to file a petition (and petition fee) under the above options (I) or (II) within TWO MONTHS of the date of this Notice (37 CFR 1.181(f)) will be treated as a constructive acceptance by the applicant of the application as deposited in the USPTO. THIS TWO MONTH PERIOD IS NOT EXTENDABLE UNDER 37 CFR 1.136(a) or (b). In the absence of a timely filed petition in reply to this Notice, the application will maintain a filing date as of the date of deposit of the application papers in the USPTO, and original application papers (i.e., the original disclosure of the invention) will include only those application papers present in the USPTO on the date of deposit.

In the event that applicant elects not to take action pursuant to options (I) or (II) above (thereby constructively electing option (III)), amendment of the specification to renumber the pages consecutively and cancel incomplete sentences caused by any omitted page(s), and/or amendment of the specification to cancel all references to any omitted drawing(s), relabel the drawing figures to be numbered consecutively (if necessary), and correct the

references in the specification to the drawing figures to correspond with any relabeled drawing figures, is required. A copy of the drawing figures showing the proposed changes in red ink should accompany with any drawing changes. Such amendment and/or correction to the drawing figures, if necessary, should be by way of preliminary amendment submitted prior to the first Office action to avoid delays in the prosecution of the application.

Replies should be mailed to: Mail Stop Missing Parts

Commissioner for Patents

P.O. Box 1450

Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE



Our Ref. 200.1133CON5

November 4, 2003

RJP/HMS/

RE: Patent Application: Benjamin OSHLACK, et al. Senal No.: To be Assigned

Herewith

Filed: For

TAMPER-RESISTANT ORAL OPIOID

AGONIST FORMULATIONS

Enclosed:

- Continuation Utility Application Transmittal (4:pages);

- Continuation Utility Application Transmitted (**pages),
- Specification (86 pages);
- Informal Drawings (3 pages);
- Copy of Executed Declaration and Power of Attorney (2 pages);
- Certificate of Express Mail (1 page);
- Preliminary Amendment (3 pages);
- Information Disclosure Statement Letter (4 pages);

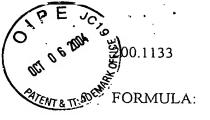
- rolling 10-1449 (21 sheets); - copies of commonly assigned pending specifications and claims -Exhibit A; and -Check in the amount of \$770.00.

WITH EXPRESS MAIL LABEL NO. EV 319058938 US

MAIL STOP: PATENT APPLICATION RECEIVED BY:







Ingredients	Amt/unit 5
	(mg)
LOADING	1 4 5 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Naltrexone HCl	5.0
Sugar Spheres (30/35	50.0
mesh)	
Opadry White Y-5-7068	2.5.
Purified Water	42.5*
OVERCOATING	· 1000 年 2000 中央
Opadry White Y-5-7068	3.02
Purified Water	17.11*
NON-RELEASE	
COATING (FOR	
RENDERING OPIOID	
ANTAGONIST	
SUBSTANTIALLY	
NON-RELEASABLE)	
Eudragit RS30D (dry wt.)	12.10
Triethyl Citrate	2.42
Talc	4.84
Purified Water	49.21*
OVERCOATING	
Opadry White Y-5-7068	4.12
Purified Water	23.35*
Total	84.0

^{*} Remains in product as residual moisture only.

10	PROCESS:	
	1. Solution Preparation	Dissolve the Naltrexone HCl in Purified Water. Once dissolved, add the Opadry White and continue mixing until a homogeneous dispersion is yielded.
15	2. Loading	Apply the above dispersion onto the Sugar Spheres using a fluid bed coating machine.
	3. Overcoating	Prepare an overcoating solution by dispersing Opadry White in Purified Water. Apply this dispersion over the sugar spheres loaded with Naltrexone HCl using a fluid bed coating machine.
20	4. Retardant Coating	Prepare the non-release coating solution by mixing the Eudragit RS30D, Triethyl Citrate, Talc, and Purified Water. Apply this
		dispersion over the loaded and overcoated sugar spheres using a fluid bed coating machine.
	5. Overcoating	Prepare a second overcoating solution by dispersing Opadry White in Purified Water. Apply this dispersion over the non-
25		release coated naltrexone spheres using a fluid bed coating machine
	6. Curing	Cure the spheres at 45°C for approximately 48 hours.